PERIMETER® C Spinal System
510(k) Summary

December 2013

I. Company:

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
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DEC 04 2013

II. Contact:

Michael Scott
Senior Regulatory Affairs Specialist

III. Proprietary Trade Name: PERIMETER® C Spinal System

IV. Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)

V. Class: II

VI. Product Code: ODP

VII. Product Description:

The PERIMETER® C Spinal System consists of spacers/cages of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion procedures. Additionally, this implant has six degrees of lordosis and the superior and inferior surfaces of the implant are designed with teeth which interact with the surface of the vertebral endplates to aid in resisting expulsion. The hollow geometry of the implants allows them to be packed with autogenous bone graft and is to be used with supplemental fixation in all procedures.

The purpose of this submission is to include additional interbody cages manufactured from medical grade titanium alloy (Ti-6Al-4V ELI) and designed with lateral windows. The lateral windows allow for visibility of bone graft placement. The subject device is offered in a non-sterile form.

VIII. Indications:

The PERIMETER® C Spinal System is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc who have had six weeks of non-operative treatment. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Additionally, the PERIMETER® C Spinal System implants are to be used with autogenous bone graft and supplemental fixation and implanted via an open, anterior approach.

IX. Identification of Legally Marketed Predicate Devices Used to Claim Substantial Equivalence:

In order to demonstrate substantial equivalence to legally marketed predicate device(s), PERIMETER® C Spinal System (K100967, S.E. 08/05/2011) is used as the primary predicate in terms of indications for use, intended use, fundamental scientific technology, and performance and technological characteristics.

AFFINITY® Anterior Cervical Cage System (P000028, Approval Date 06/13/2002, Down Classified to a Class II special control, Date of Final Order 06/12/2007), BAK/C® Cervical Interbody Fusion System (P980048, Approval Date 10/06/2004, Down Classified to a Class II special control, Date of Final Order 06/12/2007), CORNERSTONE® PSR Spinal System (K100214, S.E. 06/25/2010), and ANATOMIC PEEK™ Spinal System (K112444, S.E. 11/16/2011) are additionally used as predicates for this submission to demonstrate the material and performance of the subject device are substantially equivalent to other legally marketed interbody fusion devices.

X. Summary of the Technological Characteristics:

The subject and predicate PERIMETER® C Spinal System cages are identical in terms of indications for use, intended use, fundamental scientific technology, and performance and technological characteristics. The subject PERIMETER® C Spinal System is a modification to the predicate PERIMETER® C Spinal System (K100967, S.E. 08/05/2011). The subject devices comprises of interbody cages manufactured from medical grade titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and include lateral windows. The lateral windows allow for visibility of bone graft placement. The subject devices are to be used with autogenous bone graft and supplemental fixation. The subject implants are provided non-sterile. The PERIMETER® C Spinal System implants are implanted via an open, anterior approach.

XI. Discussion of Non-Clinical Testing:

An assessment of the device modifications was completed in accordance with Medtronic design control processes.

Mechanical testing was conducted according to FDA guidance document, "Class II Special Controls Guidance Document: Intervertebral Body Fusion Devices". For a determination of substantial equivalence, the following non-clinical mechanical tests and Finite Element Analysis (FEA) was performed:

Tests Performed	Applicable Standards
Static Torsion Testing	ASTM F2077 (Test Methods for Intervertebral Body Fusion Devices)
Static Compression Bending Testing	
Static Compression Shear Testing	
Dynamic Torsion Testing	
Dynamic Compression Bending Testing	
Dynamic Compression Shear Testing	
Subsidence Testing	ASTM F2267 (Standard Test Method for Measuring Load Induced Subsidence of the Intervertebral Body Fusion Device under Static Axial Compression)
Expulsion Testing Rationale	DRAFT ASTM F-04.25.02.02

The subject device successfully met all the predetermined acceptance criteria. Based on the results the subject intervertebral devices demonstrated that they are as safe and effective as the predicate device(s).

XII. Discussion of Clinical Testing:

No clinical testing was performed.

XIII. Conclusions Drawn from the Non-Clinical Tests:

Based on the risk analysis, test results and additional supporting documentation provided in this pre-market notification, the subject PERIMETER® C Spinal System demonstrates substantial equivalence to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek
Mr. Michael Scott
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

December 4, 2013

Re: K132584
Trade/Device Name: PERIMETER C SPINAL SYSTEM
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 25, 2013
Received: October 28, 2013

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132584

Device Name
PERIMETER C SPINAL SYSTEM

Indications for Use *(Describe)*
The PERIMETER® C Spinal System is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc who have had six weeks of non-operative treatment. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Additionally, the PERIMETER® C Spinal System implants are to be used with autogenous bone graft and supplemental fixation and implanted via an open, anterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices